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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,941	08/31/2001	Shirley I. Miekka	CI-003	8965

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EXAMINER

SMITH, JOHNNIE L

ART UNIT	PAPER NUMBER
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2881

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

8/16

Office Action Summary	Application No. 09/942,941	Applicant(s) MIEKKA ET AL.	
	Examiner Johnnie L. Smith II	Art Unit 2881	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2006.
- 2a) ☐ This action is **FINAL**.
- 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 98-135 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 98-135 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some * c) ☐ None of:
 - 1. ☐ Certified copies of the priority documents have been received.
 - 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, filed 01/26/2006, with respect to the rejection(s) of claim(s) 97-135 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of US 6,171,549 (Kent).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 98-135 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,171,549 (Kent). In reference to claims 98-100. Kent teaches a method for inactivating at least one biological contaminant or pathogen in a preparation containing albumin or a plasma protein fraction preparation comprising irradiating said preparation with gamma radiation at a rate of greater than 3.0 kGy/hr for a

time effective to inactivate at least one biological contaminant or pathogen in said preparation (see abstract and column 1 line 62-column 2 line 12).

4. In reference to claims 101 and 112-116, Kent teaches the biological materials may be diluting (with a solvent) prior to irradiation (example 4). In reference to claims 102 and 117-119, Kent teaches adding to said preparation at least one stabilizer (ethanol) in an amount effective to protect said preparation from said gamma radiation (adding such stabilizers are known in the art as shown in column 1 line 54-63, column 3 lines 3-6). In reference to claim 103, Kent shows a method for reducing the temperature of said preparation to a level effective to protect said preparation from said gamma radiation (column 2 lines 4-12).

5. In reference to claim 104, Kent teaches a method further comprising at least two of reducing residual solvent present in said preparation to a level effective to protect said preparation from said gamma radiation (abstract); adding to said preparation at least one stabilizer (ethanol) in an amount effective to protect said preparation from said gamma radiation; and reducing the temperature of said preparation to a level effective to protect said preparation from said gamma radiation (column 2 lines 4-12). In reference to claim 105, Kent teaches a method wherein said plasma protein fraction comprises albumin (column 4 lines 60-67).

6. In reference to claims 106-108, Kent teaches a method wherein said plasma protein fraction further comprises at least one protein selected from the group consisting of a coagulation protein, a lipoprotein, and a complement protein (column 5 lines 10-19).

7. In reference to claims 109-111, Kent teaches a method wherein said rate is greater than about 6.0 kGy/hr, greater than about 18 kGy/hr, or greater than about 30.0 kGy/hr, even though Kent uses low rates but teaches that higher rates are old in the art (see column 10 lines 16-31).

8. In reference to claims 120-125, Kent teaches that using various temperatures is known in the art (column 2 lines 4-21). In reference to claims 126 and 130-132, Kent teaches a method wherein said gamma irradiation is administered for a time effective to sterilize said preparation and the sterile product of such method (abstract). In reference to claims 127-129, Kent teaches the method wherein the preparation containing albumin is selected from various groups (column 4 line 60-column 5 line 19).

9. In reference to claims 133-135, Kent teaches a method for inactivating at least one biological contaminant or pathogen in a plasma protein fraction preparation comprising irradiating said preparation with gamma radiation for a time effective to sterilize said preparation (abstract).

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. All of the references cited on attached PTO 892 contain art similar to that being claimed by applicant.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Johnnie L. Smith II whose telephone number is 571-272-2481. The examiner can normally be reached on Monday-Thursday 6-4 P.M..


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John R. Lee can be reached on 571-272-2477. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JLSII

Johnnie L Smith II
Examiner
Art Unit 2881



JOHN R. LEE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2800